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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/402,713	06/13/2000	MARION J. G. BUSSEMAKERS	1619.0020001	6311

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10/02/2003

Stern, Kessler, Goldstein & Fox P.L.L.C.
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Washington, DC 20005

EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 10/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/402,713

Applicant(s)

BUSSEMAKERS, MARION J. G.

Examiner

MISOOK YU, Ph.D.

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-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2003 and 01 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,4-14 and 24-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,4-14 and 24-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 30.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 27.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: Notice to comply with sequence rules.

The Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Misook Yu.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 07/01/2003 and 04/11/2003 have been entered. Applicant in the RCE did not instruct the Office to enter applicant's submissions filed on 04/11/2003. However, the amendment has been entered because the amendment corrects antecedent base problem due to earlier canceling of the claims.

Claims 2, 4-14, 24-38 are pending (applicant is advised to note what is pending in the Office's record is different from applicant's record keeping at the page 4 line 2 of Applicant's submissions filed on 07/01/2003) and examined on merits.

Sequence Rules

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence

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And/Or Amino Acid Sequence Disclosures. 37 CFR 1.821(a) presents a definition for “nucleotide and/or amino acid sequences.” The instant application contains an unbranched specifically defined sequence of more than ten nucleotides. Note page 7 line 26, and Fig. 4 of the specification. Nucleotide and/or amino acid sequences as used in 37 CFR 1.821 through 1.825 are interpreted to mean an unbranched sequence of four or more amino acids or an unbranched sequence of ten or more nucleotides. Branched sequences are specifically excluded from this definition. Sequences with fewer than four specifically defined nucleotides or amino acids are specifically excluded from this section. “Specifically defined” means those amino acids other than “Xaa” and those nucleotide bases other than “n” defined in accordance with the World Intellectual Property Organization (WIPO) Handbook on Industrial Property Information and Documentation, Standard ST.25: Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings in Patent Applications (1998), including Tables 1 through 6 in Appendix 2 (see MPEP § 2422).

Specification

The disclosure is objected to because of the following informalities: The BRIEF DESCRIPTION OF THE DRAWINGS at pages 14-15 does not correlate with the drawings. The description says that Figures 2A-B while the corresponding drawing says 2A-2J. Note similar problems for Figs 3 and 5. New drawing is not needed for this objection. Amending the specification under the heading of BRIEF DESCRIPTION OF THE DRAWINGS to correlate what is described in the corresponding drawings would obviate this objection.

Information Disclosure Statement

The first supplemental information disclosure statement filed 2-26-2001 (Paper No. 12) has been considered. Also a copy of the second supplemental information disclosure statement filed 07/01/2003 (Paper No. 30) is attached with this Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 4-14, 24-38 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites "under high stringency conditions" but it is not clear what the metes and bounds are. The specification at page 9 line 21 describes high stringency wash conditions for nitrocellulose paper but does not define "under high stringency conditions". This rejection affects all dependent claims.

Claims 2, 4, and 8 recite "encoding prostate cancer antigen 3 (PCA3)" but it is not clear what the metes and bounds are. The specification does not define what is meant by the recited limitation. Merriam-Webster online dictionary downloaded on 9/30/2003 from URL >> m-w.com says "encode" mean to "specify the genetic code for". Voet et al at (1990, Biochemistry, John Wiley & Sons, Inc, pages 893-900) says genetic codes are triple codon specifying a corresponding amino acid. This indicates nucleic acid encoding an antigen means that said nucleic acid could be translated into a protein. The confusion arises from the fact that the specification at Sequence Listing,

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the Figures 1-5, and page 27 indicate that that SEQ ID NO:3 and 4 and several nucleic acid molecules in claim 8, for example PCA3 exon 1, do not appear to be an nucleic acid sequence specifying any genetic code. Many of the sequences in the base claims 2, 4, and 8 appear to be noncoding.

The rejection of claims 2, 6, and 7 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is **withdrawn** because the deposit statement (Paper No. 26) signed by AE. E.M. Kerckhoffs, Secretary to the Board of Directors University Hospital Nejmegen, The Netherlands, states that "Applicant advises that...". In view of the assignment of this application to University Hospital Nejmegen, and in view of the practice in Europe of considering the assignee to be the applicant, the deposit statement is seen as made by someone associated with the patent owner who is in a position to make the required assurances on availability.

Claims 2, 4-14, 24-38 are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the **written description** requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is made due to the limitations in claim 2 (e) (f) and (g) in connection of the preamble of the base claim 2, and also due to SEQ ID NO: 3 of claim 4 in connection of the preamble. This rejection has three parts. First, the preamble of base claims 2 and 4 says the instantly claimed invention is drawn to isolated nucleic acid molecules **encoding prostate**

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cancer antigen. However, the specification does not describe chemical structure(s) of prostate cancer antigen(s) is encoded by SEQ ID NO: 3 and 4. Bussenmakers et al (Cancer Res. 1999 Dec 1;59 :5975-90, note it is the inventor's own peer-reviewed publication) teach that instant SEQ ID NO: 3 and 4 might be noncoding. See the abstract. Second, claim 2 (f) appears to say complementary DNA also encodes for something. The nucleic acids disclosed in the instant application appear to be human DNA sequences. Unlike prokaryotes, the human complementary DNA (antisense) usually does not encode any protein except rare occasions. The instant specification does not teach any of the complementary DNA sequences encode anything. Third, claim 2 (g) is interpreted as drawn to a genus of various hybridizing nucleic molecules. The specification does not describe what kind of activity is associated with the genus of nucleic acid molecules being claimed, therefore the Office concludes that the specification does not describe the claimed genus. This rejection affects all dependent claims.

Claims 2, 4-14, 24-38 are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is also made due to the limitations in claim 2 (e) (f) and (g) in connection of the preamble of the base claim 2, and also due to SEQ ID NO: 3 of claim 4 in connection of the preamble. The specification fails to teach how to make the

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nucleic acid with the function specified in the preamble of the claims. This rejection has two parts. First, the specification does not teach how to make complementary, and hybridizing DNAs encoding prostate cancer antigen since the specification does not teach what activity to look for. The Office concludes that the making such nucleic acid molecules with what is being disclosed in the specification would cause undue experimentation. Second, the specification does not teach how to use SEQ ID NO: 3, and 4 to make prostate cancer antigen since they appear to be noncoding (note Bussenmakers et al above). One skilled in the art would never be able to use SEQ ID NO: 3 and 4 to make the antigen in the preamble. This rejection affects all dependent claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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Misook Yu
September 30, 2003


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1600 1600

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☒ 7. Other: *DNA sequences at page 7 line 26, Fig 4 do not have corresponding SEQ ID NOs.*

Applicant Must Provide:

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

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